

## REMARKS

Claims 26 has been canceled. New claims 27-28 are pending in the present application

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### I. The Rejection of Claim 26 under Double Patenting

Claim 26 is rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,060,305. Claim 26 has been cancelled rendering the rejection moot.

### II. The Rejection of Claim 28 under the Doctrine of Obviousness-Type Double Patenting

Claim 28 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,060,305. The Office Action stated:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claim would have been anticipated by claim 1 of the 6,060,305 patent. In other words, claim 1 falls entirely within the scope of claim 28.

Applicants submit a terminal disclaimer in compliance with 37 CFR 1.321(c). For the foregoing reason, Applicants submit that the claims overcome this rejection and respectfully request reconsideration and withdrawal of the rejection.

### III. The Rejection of Claims 26-28 under the Doctrine of Obviousness-Type Double Patenting

Claims 26-28 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 9 of U.S. Patent No. 6,180,366. The Office Action stated:

Claims 26-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 29 of U.S. Patent No. 6,180,366. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 26-28 of the instant application are anticipated by claims 5 and 29 of 6,180,366. In other words, claims 5 and 29 fall entirely within the scope of claims 26-28. Specifically, both the claims in the 6,180,366 patent and the

instant claims recite a recombinant *Fusarium venenatum* host cell of ATCC 20334 comprising a nucleic acid encoding a heterologous protein.

Preliminarily, Claim 26 has been cancelled. Applicants submit a terminal disclaimer for claims 27 and 28 in compliance with 37 CFR 1.321(c). For the foregoing reason, Applicants submit that the claims overcome this rejection and respectfully request reconsideration and withdrawal of the rejection.

**IV. The Provisional Rejection of Claims 27 under the Doctrine of Obviousness-Type Double Patenting**

Claim 27 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 100 of Application No. 09/482,788. The Office Action stated:

Claim 27 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 100 of copending Application No. 09/482,788. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 100 of the copending application anticipates claims 27 of the instant application. Claim 100 falls entirely within the scope of claim 27. Specifically, both claims recite a method for producing a heterologous protein and a recombinant *Fusarium venenatum* host cell of ATCC 20334 comprising a nucleic acid encoding a heterologous protein.

Applicants submit a terminal disclaimer in compliance with 37 CFR 1.321(c). For the foregoing reason, Applicants submit that the claims overcome this rejection and respectfully request reconsideration and withdrawal of the rejection.

**V. The Rejection of Claims 26-28 under 35 U.S.C. § 112, First Paragraph**

Claims 26-28 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Office Action states:

In *Ex parte Humphreys*, 24 USPQ2d 1255 (BD. Pat. App. & Int. 1992), it was found that the only manner in which applicants could satisfy their burden of assuring public access to the needed biological material was by making a deposit as the ability to obtain the material from a given depository prior to and after issuance of a patent did not insure that upon issuance of a patent that such material would continue to be accessible to the public. See MPEP 2404.01. CPR 1.802(b) states that public access during the term of the patent may affect the enforceability of the patent. In order to ensure that the cells are available for the life of the patent, the applicant must satisfy the deposit requirement under 37 CFR 801-1.809.

This rejection is respectfully traversed.

Applicants in the Amendment of October 24, 2002, pointed out that under 37 C.F.R. 1.802(b), "[b]iological material need not be deposited, *inter alia*, if it is known and readily available to the public...."

Applicants in the Amendment of October 24, 2002, enclosed a copy of page 178 of the ATCC catalogue for 1991 which lists *Fusarium* ATCC 20334. Also attached were pages from ATCC's website ([www.atc.org](http://www.atc.org)) that disclose the strain is commercially available and may be purchased. Clearly, these publications establish that this strain was known prior to Applicants' filing date.

Applicants enclose a letter from Elizabeth Kerrigan of the American Type Culture Collection dated July 10, 2003, which confirms that *Fusarium* ATCC 20334 is preserved in the open collection of the ATCC and currently publicly available.

Applicants submit that the microorganism recited in the claims is "known and readily available" and, therefore, Applicants do not have to provide the assurances requested.

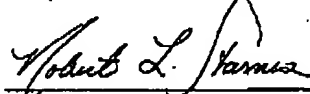
For the foregoing reason, Applicants submit that this rejection under 35 U.S.C. § 112 has been overcome and respectfully request reconsideration and withdrawal of the rejection.

#### VI. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Date: July 14, 2003

Respectfully submitted



Robert L. Stames, Ph.D.  
Reg. No. 41,324  
Novozymes Biotech, Inc.  
1445 Drew Avenue  
Davis, CA 95616  
(530) 757-8100

# ATCC

July 10, 2003

Dr. Wendy T. Yoder  
Novozymes Biotech Inc.  
1445 Drew Ave.  
Davis, Calif. 95616 USA

A global bio-science nonprofit  
organization dedicated to biological  
standards and biodiversity

10801 University Boulevard  
Manassas, Virginia 20110-2209 USA

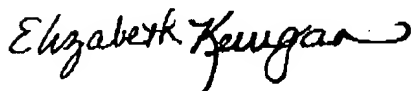
Telephone: (703) 365-2700  
Facsimile: (703) 365-2701  
Internet: <http://www.atcc.org>

Dear Dr. Yoder,

This letter is to inform you that *Fusarium venenatum* Nirenberg deposited as *Fusarium graminearum* Schwabe, anamorph strain, ATCC# 20334, is currently publicly available for purchase from our Mycology Collection. I have attached a link to the product page from our web-site:  
<http://www.atcc.org/SearchCatalogs/longview.cfm?view=fv.3273597.20334&text=20334&max=20>

It was made available as a catalog item on February 3, 1976. It was first published in our 1978 catalog, page 274. Please contact me if you have any further questions.  
Thank you.

Best Regards,



Elizabeth Kerrigan  
Product Manager  
Microbiology Products  
ATCC  
10801 University Blvd.  
Manassas, VA 20110-2209  
phone (703)365-2813  
fax (703)365-2778  
E-mail: [lkerrigan@atcc.org](mailto:lkerrigan@atcc.org)